Decision Memo for Pelvic Floor Electrical Stimulation for Urinary Incontinence (CAG-00021N)

Decision Summary

Amend *Coverage Issues Manual 65-9C* to state:

Electronic StimulatorsPelvic floor electrical stimulators, inserted into the vaginal canal or rectum, are covered as reasonable and necessary as a treatment for stress and/or urge urinary incontinence. The patient must have first undergone and failed a documented trial of pelvic muscle exercise training. These devices are not covered as initial treatment modality for stress or urge incontinence. Implanted stimulators remain noncovered.

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Decision Memo

To: File: Pelvic Floor Electrical Stimulation for Urinary Incontinence CAG-00021N

From:

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Re: National Coverage Decision
Date: October 5, 2000

This memo serves four purposes: (1) outlines the description and treatment of urinary incontinence (2) reviews the history of Medicare's coverage policies on pelvic floor electrical stimulation (PFES) (3) analyzes the relevant scientific data related to the use of PFES for stress, urge, and post-prostatectomy urinary incontinence, and (4) delineates the reasons (a) supporting a positive national coverage decision for patients with stress and/or urge incontinence who have already undergone and failed a trial of pelvic muscle exercises (PME) and (b) continuing a national noncoverage policy for those patients who have not yet undergone PME as an initial treatment modality.

Pathophysiology of Urinary Incontinence

Urinary incontinence refers to the involuntary loss of urine. Approximately 17 million adults in the US suffer from incontinence, with nearly half of nursing home residents having some degree of incontinence.[1] Women are twice as affected as men. Nearly 35% of female Medicare beneficiaries and 25% of male beneficiaries are estimated to suffer from urinary incontinence.

Although the prevalence of incontinence increases with age, incontinence is not a normal consequence of aging. Incontinence can be a distressing and often disabling state in the elderly. It can have a tremendous effect on the quality of life, as well as other health conditions. Nearly a third of all patients do not speak to their doctor about incontinence, thereby increasing morbidity. [2]

Types of Incontinence

There are various types of urinary incontinence. The two most common types are stress and urge.

- *Stress incontinence* refers to involuntary loss of urine due to inadequate urethral pressure. The patients experience urine loss during coughing, sneezing, or physical exertion.
- *Urge incontinence* refers to the involuntary loss of urine due to abnormal bladder contractions (e.g. detrusor instability). It is often associated with a sudden, strong desire to urinate. The urge gives little warning and large amounts of urine are lost.
- *Mixed incontinence* is the term used when features of both stress and urge incontinence coexist.
- *Post-prostacteomy incontinence* is a common condition among elderly Medicare patients, and is a result of the treatment of prostate cancer or benign prostatic hypertrophy.[3] It is predominantly stress or urge.

There can also be functional incontinence, which occurs in a normal urinary tract. Such causes can be multifactorial and can include medications, infections, cancer, trauma, diverticuli, and fistulas.[4]

The specific diagnosis can be made by either clinical or urodynamic testing.

Treatment Options

Treatment options include behavioral modifications, medications, vaginal cones, sacral nerve stimulation, electrical and magnetic stimulation, as well as surgery. This decision memo focuses solely on the use of pelvic floor electrical stimulation (PFES).[5]

For the purposes of this decision memorandum, PFES relates to the use of a non-implantable electrical device that delivers variable rates of current through the pelvic floor with the intent of strengthening the pelvic floor musculature. The device used in PFES generally includes an internal probe that delivers the electrical current and an external device for controlling the electrical stimulation. The intent of PFES is to stimulate the pudendal nerve in order to improve urethral closure by activating the pelvic-floor musculature. PFES is thought to improve partially denervated urethral and pelvic floor musculature by enhancing the process of reinnervation. PFES is also intended to exercise and strengthen the pelvic floor muscles.[6]

The methods of PFES vary in location (vaginal, rectal), stimulus frequency, stimulus and intensity, pulse duration, treatments per day, number of treatment days per week, length of time for each treatment session, overall time period for device use and between clinic and home settings.[7] For urge incontinence, the objective is to reinforce the inhibitory system; these inhibitory neurons operate at low frequencies, so stimulation is generally administered at 5-20 Hz. For stress incontinence, the objective is to activate the motor neurons, so stimulation is generally administered at 20-50 Hz. For mixed incontinence, the treatment sessions generally alternate between those for urge and stress incontinence.

History of Medicare's Coverage Process for Pelvic Floor Electrical Stimulation

Presently, the Medicare program has a national noncoverage policy. The Coverage Issues Manual (CIM) 65-9C states:

Electronic Stimulators*Pelvic floor electrical stimulators, whether inserted into the vaginal canal or rectum or implanted in the pelvic area, used as a treatment for urinary incontinence, e.g., as a bladder pacer or a retraining mechanism, are not covered. The effectiveness of these devices is unproven*

The topic of electrical stimulation has been discussed for several years. It was first discussed in 1994 at HCFA's Technical Advisory Committee (TAC). The TAC reviewed an Agency for Health Care Policy and Research (AHCPR) guideline on urinary incontinence, but the TAC did not believe the data in the guideline supported effectiveness. [8] The TAC focused on the fact that the report stated "Research is needed to determine the efficacy of electrical stimulation either when used alone or in combination with other management strategies....Ideal parameters for electrotherapies have not been established by controlled clinical trials, and research needs to be conducted before this technique becomes a standard treatment." Therefore, the TAC recommended the CIM be revised to state that these devices are noncovered. Previously, it had been left to carrier discretion. This issue was readdressed in March, 1996 at the TAC. Earlier in the year, AHCPR had published an update on urinary incontinence. TAC members reviewed the update, as well as results of a multi-center clinical trial, and concluded that PFES may be no better than no treatment at all, and it offered less evidence of its effectiveness than biofeedback. Therefore, the TAC voted not to revise the noncoverage policy.

In addition, the Blue Cross Blue Shield Technology Evaluation Center (TEC) performed a technology assessment on this topic in 1998 and concluded that this device did not meet the TEC criteria.[9]

Since the TAC recommendation and subsequent noncoverage decision, the manufacturers of this product have been to HCFA's Central Office several times to discuss reconsideration of the policy. Empi contracted with MEDTAP International, Inc to provide an analysis of the assessment, and provided it to the agency in 1998. [10] [11] The MEDTAP report asserted that the Blue Cross Blue Shield TEC assessment (1) misinterpreted the studies reviewed (2) excluded articles that showed effectiveness of PFES. HCFA staff reviewed this report, and met with MEDTAP representatives to discuss the report. Given the conflicting evidence and differences of opinion in the scientific and clinical community, in early 1999, it was decided by then-Director of the Coverage and Analysis Group Grant Bagley, MD, JD that this topic would be presented to the Medicare Coverage Advisory Panel (MCAC). HCFA subsequently generated an internal request for a national coverage determination, and referred the issue to the MCAC.

Technology Assessment

Prior to referral to the MCAC, HCFA ordered a technology assessment from the Blue Cross Blue Shield Technology Evaluation Center, one of the evidence-base practice centers (EPC's) of the Agency for Health Research and Quality (AHRQ). [12] The EPC's employ rigorous, up-to-date methodology for systematically reviewing the literature on a clinical topic and forming evidence-based conclusions. By following this generally-accepted methodology for performing systematic reviews, the likelihood that the conclusions are bias is minimized.

See Technology Assessment

The focus of the assessment was to answer the following questions:

1. *Compared to placebo*, is the treatment with PFES efficacious in reducing incontinence?
2. What is the efficacy of PFES as *compared to pelvic muscle exercises (PME) or alternative nonsurgical treatment*?
3. Does the *addition of PFES to PME* result in improved outcomes above that obtained with PME alone?

It is important to note that the technology assessment did *not* specifically address the effectiveness of PFES in those patients who have failed pelvic muscle exercises.

Selection of articles to be reviewed were as follows:

- Full-length peer reviewed articles
- Documented stress, urge, or mixed incontinence by physician diagnosis and urodynamic testing
- Concurrent comparison group
- Valid health outcome measures
- Adequate description of patient population

A total of 12 studies (11 published articles) were included in the assessment.

- 6 trials compared PFES to placebo
- 5 trials compared PFES to alternative treatments
- 1 trial compared PFES + PME to PME alone

The comparisons were done for stress, urge, and post-prostactectomy incontinence. The breakdown of the studies can be seen in Table 1.

	Stress Incontinence	***Urge Incontinence***	***Post-prostactectomy incontinence***
PFES vs placebo	5 studies (4 randomized) (n=243)	1 study (randomized) (n=61)	
PFES vs alternative treatments	5 studies (5 randomized) (n=260)	1 study (randomized) (n=38)	
PFES + PME vs PME alone	1 study (randomized) (n=14)		1 study (n=63)

n=number of patients
* this represents articles in technology assessment only, and does not include articles in the exclusion tables, or articles received after the Medicare Coverage Advisory Committee (MCAC) meeting

PFES vs placebo

As noted above, the majority of studies were done on stress incontinence. Of the 5 studies, 4 were randomized, and all 5 were blinded. A total of 243 patients were studied with number of patients ranging from 30-67 in each study.

Specific information on each study can be found in the technology assessment. The main outcome measures were (a) change in leaks/day as measured by a bladder diary, and (b) change in weight on a pad test. These two measures are generally agreed upon as the most appropriate outcome measures in studies on incontinence.

Overall, the data trends toward an improved outcome, with the majority of studies reporting benefit. Statistically significant results favoring PFES were reported in three of the five trials. Tables 2 and 3 show the particular results of each study. Of note, the Brubaker study, which used urodynamic measurements, may not have used the appropriate stimulation intensity to see the desired effect.

The Sand and Yamanishi studies are two of the better designed studies on PFES. The Sand study randomly assigned 52 women (on a 2:1 basis) with stress incontinence to either PFES or a sham device. After 12 weeks of home treatment, the PFES group showed a reduction in the number of leaks per week from 14.2 to 10.0, and leaks/day from 3.1 to 1.8. Patients using the sham group actually got worse. (Other studies did not show this worsening effect in a sham group.) Sand also showed a 46% improvement by pad test in the experimental group. There was a fair number of dropouts in the study, but an intent-to-treat analysis was performed. The data was statistically significant. The Yamanishi study was a randomized, double-blinded controlled trial enrolling 33 patients (28 women, 5 men). After 4 weeks of treatment, 50% patients were cured with the device vs 8.3% for the sham. 80% of patients in the PFES group showed 50% improvement versus 18% in the control group. Data was statistically significant.

Study	***PFES***	***Sham PFES***
Sand 1995	42%*	-26%
Luber 1997	14%	11%
Laycock 1993	No difference	No difference
Brubaker 1997	NR	NR
Yamanishi 1997	33%*	0%

*statistically significant

NR=not reported

Study	*PFES*	*Sham PFES*
Sand 1995	66%*	-8%
Luber 1997	NR	NR
Laycock 1993	66%*	28%
Brubaker 1997	NR	NR
Yamanishi 1997	56%*	-45%

*statistically significant

One trial (Brubaker et al 1997) studied patients with urge incontinence. The results of this trial are notable since outcome measures were pre/post-treatment urodynamic testing. Urodynamic testing is the gold standard for diagnoses. The percentage of patients with diagnosis of urge incontinence decreased from 54% to 27% after treatment, whereas the change in pre/post treatment diagnosis was 47% to 41% for the sham treatment group. Data was statistically significant. Although there may be some question of correlation between urodynamic measurements and clinical symptoms, most data points to a positive correlation.

PFES vs alternative

A total of 5 studies were conducted comparing PFES to an alternative treatment for stress incontinence. One study was conducted relating to urge incontinence. These alternatives included PME, vaginal cones, and no treatment (waiting-list control). Of the 5 trials for stress incontinence, all 5 were randomized, and blinded. A total of 260 patients were studied, with study sizes ranging from 18-107 subjects.

Specific information on each study can be found in the technology assessment. Tables 3 and 4 show the particular results of each study. Overall, some studies reported benefit, others did not. As can be seen, only one study showed statistically significant results, and this study (Bo, 1999) was in favor of PME. This study randomized 107 patients to four groups: PFES, PME, vaginal cones, and waiting-list control. All three treatment groups showed efficacy on at least one outcome measure, but improvement was consistently larger for those patients undergoing PME, sometimes twice as efficacious.

Study	*PFES*	*Alternative*
Bo 1999	30%	PME 60%* Cones 30%
Smith 1996	53%	PME 20%
Olah 1990	60%	Cones 63%
Laycock 1993	NR	NR
Hahn 1991	NR	NR

*statistically significant

Study	*PFES*	*Alternative*
Bo 1999	13%	PME 78%* Cones 30%
Smith 1996	NR	NR
Olah 1990	67%	Cones 49%
Laycock 1993	NR	NR
Hahn 1991	34%	PME 61%

*statistically significant

One trial (Smith 1996) compared PFES with an alternative (i.e. anticholinergic drug) for urge incontinence. It was randomized and enrolled 38 women. Percent of patients with at least a 50% improvement in leaks per day as measured by diary was 50% for the PFES group, and 35% for the medication group. There was no statistical difference between the groups.

PFES + PME vs PME alone

One trial compared PFES + PME to sham PFES for the treatment of stress incontinence. This trial (Blowman et al 1991) was randomized, and double-blinded. It did not show a statistical difference between treatment groups.

One trial (Moore et al 1999) compared PFES + PME to sham PFES for the treatment of post-prostatectomy incontinence. The study did not show a statistical difference between the groups as measured by a pad test.

Assessment Conclusions

The assessment made the following conclusions:

1. Evidence is not adequate to determine the efficacy of PFES for stress incontinence.
2. Evidence does not suggest that PFES is superior to alternatives for stress incontinence.
3. Evidence for PFES in urge incontinence, and post-prostatectomy incontinence is sparse.

These conclusions relate solely to the studies reviewed, which were well-designed scientific studies with a control group, that were published in peer-reviewed literature. The assessment did not state that this therapy was ineffective, but rather remarked that the data was, in their opinion, inconclusive. Such conclusions may have been different, if different studies were reviewed. Of note, at least one other literature review (Berghmans et al is discussed later in this document) arrived at a different conclusion for women with stress incontinence.

The assessment did not make any conclusions about the effectiveness of PFES in those patients who have failed PME.

Additional Articles Not Included as Part of the Assessment

Twelve additional articles were included for the panel to review. These studies are part of the "Exclusion articles" which were not included as part of the assessment review by Blue Cross Blue Shied TEC, but were reviewed by HCFA staff and sent to the MCAC for consideration. These studies did not meet the inclusion criteria for the technology assessment, but were frequently cited by proponents of PFES as demonstrating effectiveness. Eleven of the twelve were case series, and one was a questionnaire. See Exclusion Tables for the specifics of these articles.

8 studies focused on stress incontinence. A variety of outcome measures were used, with some looking at change in leaks/day or leaks/week, or a standard pad test. Of the 4 studies that measured leaks per some defined time frame, as record by a patient diary (Dumoulin, Miller, Richardson, and Siegel), 2 showed a statistically significant improvement. Of the 2 studies that measured pad test weight as an outcome (Dumoulin and Richardson), one showed a statistically significant improvement. The main concern with these studies was that most lacked an adequate control group, thus rendering causality difficult to determine. Uncontrolled case series may be informative, but are prone to a range of biases, and generally require confirmation by controlled trials.

Of note, there has been an additional article on urge incontinence that was not reviewed by the panel. This study appeared in March 2000 in Urology, prior to the MCAC meeting, but was not included as part of the committee materials since materials had already been distributed. [13] This study enrolled 68 patients (average age, 70 years), 29 men and 39 women with detrusor overactivity. 32 patients in the active group, and 28 in the sham group completed the study. They received 15 minutes of therapy twice a day for four weeks. Efficacy was evaluated on the basis of a frequency/volume chart and urodynamic study. At the end of the study, 7 patients (22%) were cured, and 26 (81%) improved. Thirteen patients remained cured/improved for 8.4 months. Data was statistically significant.

In addition, a systematic review on PFES in the treatment of incontinence was published in 1998.[14] This was not included as part of the assessment since it was not a clinical trial. This review included many of the same articles the BCBS TEC included, although the articles selected were not exactly the same. Berghmans concluded that there was strong evidence for efficacy of PFES versus sham, but no clear evidence that PFES was better than other therapies.

Medicare Coverage Advisory Panel

On April 13, the Medical/Surgical Procedures Panel of the MCAC met to discuss the topic of PFES for the treatment of incontinence.[15] This panel included nationally recognized experts in health services research, a urologist and former president of the American Urological Association, a urogynecologist, an obstetrics/gynecologist, and a nurse expert in incontinence. The panel was sent the technology assessment, the exclusion tables, all articles, and a catalogue of additional materials received by the agency for the panel to review. See Catalogue of Materials (which included such items as the *AHCPR Guidelines on Urinary Incontinence*, position statements by specialty societies, letters by individual physicians and patients).

During the panel meeting, more than fifteen people spoke, representing a wide range of interests, including professional societies, physicians and other providers, device companies, and patients.

During the final panel recommendations period, the panel was asked to vote on a series of questions. If the panel was to vote affirmatively on question number 1, they were to proceed to questions 2, 3, and 4. If the panel voted not to affirm any part of question 1, then they would not be able to proceed to answering questions 2, 3, and 4.

1. Is the scientific evidence adequate to draw conclusions about the effectiveness of:

- PFES compared to placebo
- PFES compared to pelvic muscle exercises (PME) or alternative non-surgical techniques
- PFES + PME compared to PME alone in routine clinical use in the Medicare populations for the following three indications: 1) stress incontinence, 2) urge incontinence, and 3) post-prostatectomy incontinence?

The following points were to be considered when answering this question:

Adequacy of study design:

Is there evidence that the studies do not over or underestimate the effect of the intervention? For example, do the patients who received the intervention differ systematically from those in the control group in ways that might affect outcomes?

Do the studies permit conclusions about the health outcome of the technology?

Consistency of results: Are the results of the studies consistent or are they contradictory?
Applicability to the Medicare population: Are the results of the studies applicable to the various Medicare populations?
Applicability beyond the research setting: Are the results likely to apply in routine clinical settings?

2. If the evidence is adequate to draw conclusions, what is the size, if any, of the overall health effect of PFES compared to placebo for the treatment of urinary incontinence? Please place the size and direction of effectiveness into one of the following seven categories:

Categories of Effectiveness

- *Breakthrough technology:* The improvement in health outcomes is so large that the intervention becomes standard of care.
- *More effective:* The new intervention improves health outcomes by a significant, albeit small, margin as compared with established services or medical items.
- *As effective but with advantages:* The intervention has the same effect on health outcomes as established services or medical items but has some advantages (convenience, rapidity of effect, fewer side effects, other advantages) that some patients will prefer.
- *As effective and with no advantages:* The intervention has the same effect on health outcomes as established alternatives but with no advantages.
- *Less effective but with advantages:* Although the intervention is less effective than established alternatives (but more effective than doing nothing), it has some advantages (such as convenience, tolerability).
- *Less effective and with no advantages:* The intervention is less effective than established alternatives (but more effective than doing nothing) and has no significant advantages.
- *Not effective:* The intervention has no effect or has deleterious effects on health outcomes when compared with "doing nothing," (e.g., treatment with placebo or patient management without the use of a diagnostic test).

3. If the evidence is adequate to draw conclusions, what is the size, if any, of the overall health effect of PFES compared to pelvic muscle exercises (PME) or alternative non-surgical techniques for the treatment of urinary incontinence?

4. If the evidence is adequate to draw conclusions, what is the size, if any, of the overall health effect of the addition of PFES to PME compared to PME alone?

On questions #1, the panel voted:

- 8-1-1 (one negative, one abstention) that there was insufficient evidence to determine the effectiveness of PFES compared to placebo for the treatment of stress incontinence in the Medicare populations. 10-0 that there was insufficient evidence to determine the effectiveness of PFES compared to placebo for the treatment of urge incontinence and post-prostactetomy in the Medicare populations.

- 10-0 that there was insufficient evidence to determine the effectiveness of PFES compared to alternative nonsurgical techniques for the treatment of stress, urge, or post-prostactectomy incontinence in the Medicare populations.
- 10-0 that there was insufficient evidence to determine the effectiveness of PFES + PME compared to PME alone for the treatment of stress, urge, or post-prostactectomy incontinence in the Medicare populations.

The panel was not asked to address the question of adequacy of evidence for the effectiveness of PFES in patients who have failed PME.

Since the panel voted that there was insufficient evidence to determine the effectiveness of PFES, they did not proceed to Questions 2, 3, 4. The panel did not vote to say that PFES was ineffective, but rather voted to say that they could not definitively conclude, based on the type and presentation of materials submitted, whether PFES was effective or ineffective. In addition, several panel members did comment that if they were to vote specifically on Medicare coverage, they would have voted "yes." Some panelists noted that if they were to have considered coverage, they would have placed greater emphasis on the testimony of professional organizations, clinical experts, and the public.

On June 6, 2000 the MCAC Executive Committee met and ratified the recommendations of the Medical/Surgical Procedures Panel. This decision was submitted to HCFA by Dr. Harold Sox on July 25, 2000.

Since the MCAC meetings, HCFA has continued to meet with physicians and other providers groups, manufacturers, and other interested parties, providing additional information to help in the decision-making process.

HCFA's Analysis

In addressing the issue of a national noncoverage policy for the use of PFES in the treatment of urinary incontinence, the following questions arise:

- **Is the evidence adequate to determine the effectiveness of PFES in the treatment of stress, urge, and post-prostatectomy incontinence?**
- **Is the evidence applicable to the Medicare population?**
- **Are the outcomes clinically and functionally relevant?**
- **Who is the appropriate patient population?**

When evaluating the adequacy of the evidence, HCFA has examined the entire body of clinical and scientific information. This body of evidence included the AHCPR guideline, the technology assessment, exclusion tables, recommendations of the MCAC, position statements of specialty societies, and all other information received by the agency on this topic. No one piece of information was exclusively relied upon, but rather the entire breadth of information was carefully considered.

As mentioned earlier in the text, a guideline on urinary incontinence was published by the Agency for Health Care Policy and Research. This guideline was initially written in 1992 with an update in 1996. The guideline gave a Level B Recommendation to the following two statements:

Pelvic floor electrical stimulation has been shown to decrease incontinence in women with SUI.
Pelvic floor electrical stimulation may be useful for urge and mixed incontinence.

Level B: Recommendation is supported by scientific evidence from properly designed and implemented clinical series that support the guideline development.[16]

Again, AHCPR defines strength of evidence as level B if there is fair research-based evidence to support the recommendation. Although Level B evidence is slightly better than Level C, it falls short of an A rating for strength of evidence which would require good research-based evidence to support the recommendation. Of note, the guideline specifically states that "further research is needed to determine the efficacy of PFES used alone, or in combination with other therapies", reflecting the expert group's recognition of the limited scientific evidence to support the recommendation. Since the development of this guideline, at least 10 new studies have been published, and all were reviewed in the technology assessment. Prior to that time, only 2 RCTs had been conducted. In addition, the guideline states that treatment using stimulation requires monitoring by a health care provider. Nowadays, this device is primarily used as durable medical equipment, and as such, monitoring would not be available.

Some persons at the panel meeting and through letters to the agency, have suggested that since the AHCPR guideline had already created a guideline, why doesn't HCFA just accept the AHCPR report? AHCPR guidelines are an important consideration in coverage determinations; however, they do not guarantee coverage. Rather, when a guideline exists, it needs to be viewed along other scientific data. A national coverage decision must not only be based on evidence to support reasonable clinical benefit but must also be based on evidence which allows coverage and non-coverage based on the appropriate selection of modalities, clinical conditions, and patient characteristics.

In addition, there has been a wealth of new information available since the guideline. This assessment takes into account all of the information that AHCPR considered when first issuing the guideline, and also considers an expanded and more comprehensive body of literature.

Position statements

Position statements by specialty societies are an important consideration in determining a national coverage decision. Although it is not possible to comment on all of these statements, the following represents a summary of the national organization's comments on the topic of PFES.

The American College of Obstetricians and Gynecologists (ACOG)

ACOG recognizes that there is bias and many unanswered questions regarding the effectiveness of PFES that most likely require better designed and better executed studies. Nonetheless, their opinion is that PFES may be efficacious for both stress and urge incontinence in women in whom traditional treatment approaches have failed. They do, however, state that it may be no better than other therapies available, including PME, bladder retraining, and medications for urge incontinence. ACOG supports the availability of PFES devices for patients because they are convenient, have no side effects, and can be used in the convenience of the home avoiding travel to the physician's office and time away from work.

American Physical Therapy Association (APTA)

APTA cites several studies which demonstrate that electrical stimulation can significantly reduce UI, and they strongly support its use, particularly in patients who are not capable of voluntary muscle contractions. The APTA feels that PFES is a valuable treatment that improves efficiency of incontinent care along with pelvic floor muscle strengthening and behavioral techniques.

American Urologic Association (AUA)

The AUA based its position statement upon a literature review of the evidentiary support for specific therapies for the treatment of UI. AUA formed a committee to examine the scientific evidence; this committee felt that there was not strong consensus about the effectiveness of vaginal, suprapubic, and/or anal electrical stimulation for stress, urge, or mixed incontinence. The committee rated the evidence for isolated electrical stimulation as level 5 (less effective but with advantages) and for some data, level 4 (as effective but with no advantages). Additionally, they urged further randomized trials be done, including a comparison of electrical stimulation to behavioral modification programs within various populations.

American Urogynecologic Society (AUGS)

AUGS supports the use of PFES therapy as a unique, low risk therapy which strengthens the body's natural continence mechanisms by stimulating particular pudendal nerve reflexes. They state that PFES is nonsurgical, provides a potential cure, and is of relatively low cost. They recommend initial diagnostic screening to ensure appropriate patient selection and defined patient selection criteria, including intact cognitive function, for patients who may be eligible to receive PFES.

Association for Applied Psychophysiology and Biofeedback (AAPB)

The AAPB expressed concern that PFES and biofeedback were being viewed as "equal topics." The association pointed out that there are fundamental differences between the two, including the mechanisms of operation, clinician education and training required, and relevant clinical outcomes. The AAPB state that electrical stimulation research has a considerably poorer track record than biofeedback, and that the overwhelming majority of electrical stimulation studies achieve considerably less symptom reduction than biofeedback.

Society of Urologic Nurses & Associates (SUNA) and the Wound, Ostomy, and Continence Nurses Society (WOCN) Continence Coalition

The Continence Coalition, consisting of members of SUNA & WOCN, supports the use of transvaginal/transrectal electrical stimulation in selective cases. They testified that based on the available evidence, maximal electrical stimulation is indicated for urge UI, frequency and urgency, and for selected patients undergoing pelvic muscle rehabilitation with biofeedback. The coalition recommends a cost effective, outcome oriented, step-wise approach for treating UI, and feels that PFES is effective in reducing UI and in decreasing associated costs. The coalition recognizes the potential misuse of these devices, but maintains that these procedures should be reimbursed when appropriately applied.

National Association for Continence (NAFC)

NAFC supports the Society of Urologic Nurses & Associates (SUNA) and the Wound, Ostomy, and Continence Nurses Society (WOCN) Continence Coalition position statement supporting coverage of PFES. Furthermore, NAFC supports the development of uniform clinical criteria which would be consistent with national policy and include access to clinical services regardless of type of residence, e.g. home health, nursing, home, assisted living, rehabilitation and outpatient settings.

Summary of Position Statements

In general, the position statements are supportive of PFES, particularly for those women who fail PME. At the same time, the majority of societies acknowledge that it is unclear whether PFES has any added benefit over PME or other therapies. Almost all association representatives acknowledge that patients should have a choice of therapeutic options, especially noninvasive, since the alternative is surgery.

Summary of Evidence

To summarize the literature, a total of 25 studies were evaluated; 13 were randomized control trials, 12 were case series. Over 80% of the studies evaluated the effectiveness of PFES in stress incontinence. Of the 13 randomized studies, 5 showed benefit of PFES that was statistically significant. The others either showed no difference (or difference was not statistically significant), or greater benefit of PME over PFES. Of the 12 case series, 9 showed some benefit. The majority of other studies had no comparison group, so it is difficult to determine if these patients would have improved without the use of PFES.

The main outcome measures have been discussed earlier and are listed in Tables 2-5. When evaluating these outcome measures such as reduction in leaks/day, it is important to determine whether they are functionally and clinically relevant. It is also useful to look at the cure rates, and > 50% improvement rate for this therapy. Table 6 lists the cure rates for those studies that listed one of the main outcome measures discussed earlier. Cure was generally defined as 100% decrease in incontinence (i.e. no incontinent episodes over a defined time period). 50% improvement was generally defined as 50% decrease in incontinent episodes, or reduction by 50% in the weight on a pad test.

Study	***% cure***	***> 50% improvement***
Bent	4 % (2/45) (subjective)	58% (26/45) (subjective)
Blowman	100% (7/7) 52% cure rate in 6 control patients doing PME	NR
Bo	28% (n=32) PFES 44% (n=29) for PME	30% PFES group 60% PME
Caputo	NR	76% (58/76)
Eriksen	36% 2- yr followup 20/55	20% (11/55)
Hahn	10% cure PFES 40% cure PME	50% PFES (n=10) 80% PME (n=10)
Kralj	50.5% (56/111)	23.4% (26/111)
Laycock	4.3 % cure PFES (n=23) 17.6% cure PME (n=23)	
Luber	10% cure PFES (n=26) 17% cure sham (n=28)	
Moore	NR	66% PFES + PME (n=22) 85% PME (n=20) 73% control (n=21)
Olah	11.1% (n=36) PFES 12.2% (n=23) PME	

Study	*% cure*	*> 50% improvement*
Richardson	23% (n=13)	
Sand	20% cure PFES 12% cure sham	46% PFES 18% sham
Siegel	28% (19/68)	69% (46/76)
Smith	22%(n=9) PFES 11% (n=9) PME	44% PFES 33% PME
Yamanishi	50% PFES (n=20) 8.3% Sham (n=13)	80% PFES 18% Sham

The majority of patients experienced a reduction of a few leak episodes per day. Although the majority of patients remained incontinent, a reduction in a few episodes per day can have enormous functional relevance.

It is important to acknowledge that not all studies are given equal weight in considering coverage. Rather, there is a hierarchy of evidence; well-designed are given more consideration than less rigorous studies. In this particular example, there have been 25 studies with over 700 patients studied. Although there are conflicting studies on the effectiveness of PFES for stress incontinence, the better-designed studies appear to show benefit. The majority of studies also showed statistical significance when compared to placebo. Studies comparing PFES to alternative therapies did not show superiority of PFES, with one study showing PME nearly twice as effective as PFES. However, the studies did show PFES was effective.

There is also reasonable data on urge incontinence. Both Yaminishi and Brubaker were well-designed studies that showed effectiveness. Combined with the Smith study and several studies from the exclusion tables, one can conclude that PFES works for urge incontinence as well. In addition, there is biologic plausibility that if this device works for stress incontinence, it should also work for urge, albeit at a different frequency. As with the studies for stress incontinence, we would have preferred to see studies with a larger number of patients, longer followup and more rigorous data analysis.

Considering the total body of scientific literature which at times was conflicting either because of study design or low power to detect differences, the MCAC panel believed that the empirical evidence presented was inadequate, to determine conclusively, the effectiveness as a primary treatment modality. At the same time, professional societies' consensus statements, expert opinions, and additional analysis strongly suggests the value of PFES, particularly for those patients who have undergone and failed a trial of PME. Therefore, we will cover this therapy for those patients who have undergone and failed PME, and noncover PFES as a primary (i.e. initial) treatment modality.

We encourage physicians, patients, manufacturers, and other interested parties to review the recent National Coverage Determination on Clinical Trials. This policy details the implementation of President Clinton's Executive Memorandum on covering routine patient care costs for Medicare patients enrolled in clinical trials.[17] Such provision of Medicare funding is designed to help the Medicare program answer questions about the effectiveness of therapies on Medicare patients. It would be particularly interesting to see a clinical trial comparing the multiple behavioral therapies against each other, as well as to surgery. We would be interested in looking at this therapy again within the next three years, with the hope of possibly expanding coverage for patients as an initial therapy based on high-quality, rigorously designed studies.

Summary

Urinary incontinence remains a significant medical problem for a large number of beneficiaries. After reviewing the entire body of scientific and clinical literature, the position statement by specialty societies, discussion at the MCAC, and numerous letters from individual patients and physicians, we can conclude that PFES is effective for those patients with stress and/or urge incontinence. Such patients must undergo a trial of pelvic muscle exercise training prior to use of the device.[18] Patients with post-prostactectomy incontinence may receive this therapy as long as they have undergone and failed a trial of PME, and have their condition diagnosed as stress/urge. We encourage additional clinical trials to determine the exact role of this therapy, especially in relation to other incontinence treatments.

DECISION:

Amend *Coverage Issues Manual 65-9C* to state:

Electronic StimulatorsPelvic floor electrical stimulators, inserted into the vaginal canal or rectum, are covered as reasonable and necessary as a treatment for stress and/or urge urinary incontinence. The patient must have first undergone and failed a documented trial of pelvic muscle exercise training. These devices are not covered as initial treatment modality for stress or urge incontinence. Implanted stimulators remain noncovered.

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1 Urinary incontinence is a leading cause of admission to nursing homes.

2 In a recent study, although 75% of incontinent men expressed interest in being evaluated and treated, only 32% had brought up the problem with their primary care provider. Smoger SH, et al. Annals of Internal Medicine 2000;132:547-551

3 Approximately 8% of patients who undergo transurethral resection of the prostate suffer from some degree of post-prostactectomy incontinence.

4 The classic mnemonic is DIAPPERS: delirium, infection, atrophic urethritis, pharmacologics, psychologic, endocrine, restricted mobility, stool impaction. See Resnick NM, Yalla SV. Management of urinary incontinence in the elderly. New England Journal of Medicine 1985;313:800-805.

5 Decision Memorandum on Biofeedback for Treatment of Urinary Incontinence (CAG-00020) can be found at http://www.cms.hhs.gov/coverage

6 Current PFES devices have 510 (k) clearance from the Food and Drug Administration (FDA)

7 Although PFES is primarily used as Durable Medical Equipment, this document addresses the use of PFES in any setting.

8 Urinary Incontinence Guideline Panel. Urinary incontinence in adults: clinical practice guideline. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services, 1992.

9 The five criteria are: (A) The technology must have final approval from the appropriate government regulatory bodies. (B) The scientific evidence must permit conclusion concerning the effect of the technology on health outcomes. (C) The technology must improve the net health outcome. (D) The technology must be as beneficial as any established alternative. (E) The improvement must be attainable outside the investigational settings

10 Empi, St. Paul Minnesota is a major manufacturer of the pelvic floor electrical stimulators.

11 MEDTAP International, Inc is a technology assessment firm located in Bethesda, MD.

12 AHRQ was formerly AHCPR. There are 12 EPC's.

13 Yamanishi T, Yasuda K, et al. Randomized, double-blind study of electrical stimulation for urinary incontinence due to detrusor overactivity Urology 55:353-357, 2000.

14 Berghmans LC, Hendriks HJ, Bo K, et al. Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials. British Journal of Urology, 82:181-191, 1998.

15 On April 12, the same panel met to discuss the effectiveness of biofeedback for the treatment of incontinence.

16 Level A: Recommendation is supported by scientific evidence from properly designed and implemented controlled trials providing statistical results that consistently support the guideline.
Level C: Recommendation is supported by expert opinion.
The ratings represent the strength of the supporting research evidence, not the strength of the recommendation itself.

17 This memo can be found at http:/www.cms.hhs.gov/coverage

18 Adequate trial of PME will be defined in an upcoming coverage instruction to Medicare contractors.

Catalogue of Materials
Exclusion Tables

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